UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,327	12/01/2000	Glen Jorgensen	350930-0117 ZQI-102 CON1	4739

48329 7590 02/18/2010

FOLEY & LARDNER LLP
111 HUNTINGTON AVENUE
26TH FLOOR
BOSTON, MA 02199-7610

EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/728,327	JORGENSEN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-45 and 49-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-45 and 49-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2010 has been entered.

Claim Status

Claims 37-45 and 49-63 are pending.

Claims 1-36 and 46 are cancelled.

Claims 62 and 63 are new.

Claims 37-45 and 49-63 have been examined.

Claims 37-45 and 49-63 are rejected.

Priority

This application was filed on 01 December 2000 and is a continuation of Application No. 09/082201, filed on 20 May 1998 and claims priority to earlier filed Provisional Application No. 60/047,213, filed on 20 May 1997.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This is a new matter rejection.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a biological cell processing system that comprises a supply module; a cell module; a processing module having a processing chamber; a control module that changes the volume of the processing chamber; a fluid distribution module with a plurality of channels and valves; and a plurality of sensors. In the embodiment of claim 47, the processing module further comprises a variable volume processing chamber. A review of the specification and claims as originally filed fails to disclose a processing module having a processing module whose volume is controlled by the control module and a further variable processing module. The specification discloses a processing module having a single processing chamber (p. 5, line 30-p. 6, line 3). The instant claim recites a processing module having a processing module whose volume is controlled by the control module and a further variable processing module and is therefore new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection has been modified as necessitated by amendment.

Claims 37-41, 44-48, 51-54, and 56-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei.et al. (US PAT 6,544,727) in view of Brown (US PAT 4,530,691) in view of Kobashi (U.S. PAT 5,428,993), in view of DeVries (US PAT 4, 379, 452) and in view of Siegal (S.S. PAT 4,450,375).

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution

module and a plurality of sensors. In some embodiments, the sensors include pressure, optical, mass flow, temperature, volume determination or volume detection devices. In some embodiments, supply containers store process chemicals. In some embodiments, process chemicals are selected from the group of citric acid, sodium phosphate, sodium chloride, water, polyethylene glycol, saline, isotonic buffers, glycan modifying enzymes, and glycan modifying enzyme buffers . In some embodiments, the processing module comprises a centrifuge system. In some embodiments, the processing module includes a heat transfer system. In some embodiments, the processing module includes a processing chamber. In some embodiments, the processing module includes a variable-volume processing chamber. In some embodiments, the processing module includes an expressor system. In some embodiments, the system comprises a waste module. In some embodiments, the fluid distribution module comprises a plurality of pumps adapted to the control module and the supply container. In some embodiments, the fluid distribution module comprises a pump for transferring fluid through the fluid distribution module.

Hei discloses a system for the decontamination of biological fluids (e.g., blood) (abstract and col. 66-68). Hei discloses a supply module (fig. 51, elements 508, 539, and 560). Hei discloses a cell module (fig. 5 I, elements 500, 528, and 538). Hei discloses a processing module (e.g., element 538 of fig. 51; a block disclosed on fig. 1 and 3; an element where blood and a chemical is mixed on fig. 206-C). Hei discloses a control module (fig; 5 1, element 550). Hei discloses a plurality of conduits connecting the supply module to the processing module, and the cell module to the processing

module (fig. 49-5 1 and 20A-C). Hei discloses a plurality of valves adapted to the control module and other modules (ports, see fig. 49-51,20A-C, and 37). Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids (col. 65, line 30-47). Hei disclose controlling temperature (col. 71, line 63-65; col. 72, line 55-64), flow (col. 66, line 40-65) and volume (col. 68, line 14-40) and an optical device (col. 100, line 28-38). Hei discloses supply containers containing process chemicals (fig. 20, 37, and 49-51; col. 68, line 14-67). Hei discloses phosphate salts, HEPES, citrates, physiological buffers, and anticoagulants (col. 69-70, col. 66, line 40-44). Hei discloses sterile docking, sterile filters, resin (chemical), sterile bags, sterile tubes, sterile tubing, and housing (col. 97, line 29-38 and claim 28). Hei discloses an inline filter (claims 1 and 21). Hei discloses a centrifuge system (fig. 49-51, element 520). Hei discloses a heat transfer system (col. 72, line 53-67). Hei discloses a processing chamber (element 538, fig. 51 and fig. I). Hei discloses a variable-volume processing chamber (fig. 20 and 37; col. 97, line 40-65). Hei discloses an expression system (col. 97, line 40-67). Hei discloses a waste module (a mesh pouch) (col. 121, line 45-61). Hei discloses pumps (elements 51, 6, 506, 536, 526, and 556 of fig. 51). Hei discloses the blood cells as being erythrocytes (col. 12, line 18).

Hei does not show a variable volume processing chamber that is under control of a controller.

Brown et al. shows an apheresis system comprising a variable-volume processing chamber and a controller that controls the volume of the processing chamber (Abstract). Brown et al. Shows the chamber advantageously provides an area

of a blood sedimentation surface that is greater than an interface surface that maximizes blood cell separation and minimizes platelet separation during red blood cell separation and collection (abstract).

Although Hei discloses sensors for calculating weight and volume of reinfused fluids and defining quantity of blood cells (col. 68, line 14-24; col. col. 65, line 30-47), Hei does not specifically disclose a weight sensor or confirming the correct delivery of a chemical by measuring a change in weight. Hei et al. does not show a fluid distribution module comprising a plurality of ports.

Kobashi discloses a weight sensor for chemical reagents to be used in automatic analyzers that confirms correct delivery of a chemical by measuring change in weight (for example, column 2, lines 1-25).

DeVries shows fluid distribution through conduits for processing cells. DeVries shows the fluid distribution module comprises a plurality of conduits (figure 4). DeVries shows the system is closed to environmental contaminants and providing for sterile processing (col. 2, lines 30-32). DeVries shows the fluid distribution module comprises a pump (col. 5, line 50-53). DeVries shows the plurality of conduits comprises a single use disposable device (col. 3, line 50). DeVries shows an advantage of closed fluid distribution module is that it simplifies the handling of complex fluid systems and protects the system from contamination from the environment (col. 2, lines 32-35).

Hei in view of Kobashi and in view of DeVries do not show a plurality of sealed channels in fluid communication with the plurality of ports for transferring fluid from one port to another port of the plurality of ports at least a portion of each of the plurality of

sealed channels defined by a flexible membrane; a plurality of valves, each valve of the plurality of valves associated with a respective port and aligned for displacement of the flexible membrane to control transfer of fluid, the valves adapted to the control module.

Siegal shows fluid control module comprising a plurality of channels and ports. Siegal shows that the channels are in fluid communication with the plurality of ports. The ports are capable of being connected to conduits. Siegal shows a portion of the channels is defined by a flexible membrane (col. 2). Siegal shows a plurality of valves. Siegal shows each valve of the plurality is associated with a port and aligned such that displacement of the flexible membrane controls fluid transfer (figure 5). Figure 5 shows an exploded view of the Siegal fluidics control module. Member 24' is the flexible membrane. Members 22' indicate the plurality of channels. Members 16a-d are the ports. Members 29a-d form a plurality of valves in combination with the flexible membrane. Siegal shows that the valves are adapted to a control and the operation of the valves is regulated by the control by an electrical control signals on a plurality of piezoceramic benders that cooperate with an impacting member to regulate fluid transfer (col. 3, line 40-53). Siegal shows that the fluidics control module piezo-electric transducer is outside the valve reservoir such that the transducer does not contact the fluid to provide a structure that is simple, economical to manufacture and highly effective for the intended purpose of rapidly and accurately controlling fluid flow (col. 1, line 37-42). Siegal suggest the fluidics control module can be adapted to biomedical applications (col. 5, line 23).

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include a processing chamber with a controllable variable-volume of Brown et al. because Brown et al shows a variable-volume processing chamber advantageously provides an area of a blood sedimentation surface that is greater than an interface surface that maximizes blood cell separation an minimizes platelet separation during red blood cell separation and collection. It would have been further obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include the reagent weight sensor of Kobashi. One of ordinary skill in the art would have been motivated to do this because, as suggested by Kobashi, it can prevent the wasting of reagents (for example, see abstract). It would have further obvious to modify the system of Hei et al. and the reagent weight sensors of Kobashi et al. with the fluid distribution module of Siegal and the fluid distribution via conduits of DeVries because Siegal shows an advantage of the fluid distribution module is that it is simple, economical to manufacture and highly effective for the intended purpose of rapidly and accurately controlling fluid flow.

Response to Argument

Applicant's arguments filed 22 January 2010 have been fully considered but they are not persuasive. Applicant argues that findings of fact were not presented such that applicant was not apprised of the reasons of rejection. The argument is not found persuasive because findings of fact were presented. Applicant argues that an obvious to try rationale was provided. The argument is not persuasive. No such rationale was provided in the rejection above. The rationale provided above provides a TSM rationale

with a showing of explicit advantages for the combination of components. Applicant argues that Hei, in view of Kobashi in view of DeVries, and in view of Siegal fails to show the claim limitations as amended. The argument is not persuasive. Brown shows a controllable variable-volume processing chamber having a moveable wall.

The following rejection has been modified as necessitated by amendment.

Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above, and further in view of Matkovich, US 5,126,054.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, filter with a median pore of about 0.2 microns is positioned between the supply module and the processing module. In some embodiments, the process chemicals are sterile. In some embodiments, a leukocyte depletion filter is positioned between the cell and processing modules.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal shows the system of claims 37-41, 44-48, 51-54, and 56-61, as set forth above.

Hei discloses a filter (claims 1 and 21), but Hei, in view of Kobashi et al., in view DeVries, and in view of Siegal do not disclose a filter having a median pore diameter of about 0.2 microns and a leukocyte depletion filter.

Matkovich discloses the filtration of blood components into a receiving bag (col. 1, line13-17 and claim 1). Matkovich further discloses removing leukocytes by filtration from blood (leukocyte depletion) (col. 1, line 13- 17; col. 5-6, bridging paragraph). Matkovich discloses a filter having 0.2 micron pores (claims 5 and 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above to use a filter to deplete leukocytes, such as taught by Matkovich, where the motivation would have been to remove harmful components, as taught by Matkovich.

Response to Arguments

Applicant's arguments filed 22 January 2010 have been fully considered but they are not persuasive. Applicant argues that Hei in view Brown, in view of Kobashi and in view of DeVries and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63, and in further view of Matkovich does not show a controllable variable-volume with a moveable wall. The argument is not persuasive because Brown shows a controllable variable-volume processing chamber with a moveable wall.

The following rejection has been modified as necessitated by amendment.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above, and further in view of Burney et al. (U.S. Pat. 3478673) and in view of Wrasidlo et al. (U.S. Pat. 4937196).

Claim 49 is directed to a compressor, an air reservoir, and a filter. In claim 50, the filter of claim 49 has a 0.2 micron pore size.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above show a system for processing biological cells.

Hei,, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal above do not show a compressor, air reservoir, or 0.2 micron filter.

Burney et al. shows that a source of compressed air can be generated and maintained using a compressor and air reservoir (col. 3, line 27-28). Burney shows that the stored air is cleaned by passing the air through a filter (col. 3, line 20-23).

With respect to claim 50, Burney et al. does not show a 0.2 micron filter.

Wrasidlo et al. is directed to a system from cell processing. Wrasidlo et al. shows that a 0.2 micron filter fitted to an air conduit is pumped into a reservoir leading to pressurization of the reservoir (col. 11, line 28-35). Wrasidlo et al. discloses that the 0.2 micron filter assures that sterile air is introduced to the reservoir (col. 11, line 32-34).

It would have been obvious to one of ordinary skill in the art to modify the system of Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above with the compressor, air reservoir and 0.2 micron filters to provide a source of sterile air of Burney et al. and Wrasidlo et al. because all the claimed elements were known in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing

more than predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed 22 January 2010 have been fully considered but they are not persuasive. Applicant argues that Hei, in view Brown, in view of Kobashi and in view of DeVries and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63, and in further view of Burney and in view of Wrasidlo et al. does not show a controllable variable-volume with a moveable wall. The argument is not persuasive because Brown shows a controllable variable-volume processing chamber with a moveable wall.

The following rejection has been modified as necessitated by amendment.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi et al., in view of Brown, in view DeVries, and in view of Siegal as applied to claims 37-41, 44-48, 51-54, and 56-63 above, and further in view of Hudak, US 5,641,637.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, blood cells are A, B, or AB genotype.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal shows the system of claims 37-41, 44-48, 51-54, and 56-63, as set forth above.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal above do not disclose the blood cell genotypes A, B, or AB.

Hudak discloses a method for preparing cells. Specifically, Hudak discloses rare genotype cells (e.g., AB genotype) (col. 2, line 45-52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei, in view of Kobashi et al., in view DeVries, and in view of Siegal applied to claims 37-41, 44-48, 51-54, and 56-63 above to use AB cells, such as taught by Hudak, where the motivation would have been to provide hospitals with rare cell genotype blood, as taught by Hudak, col. 2, line 45-52.

Response to Arguments

Applicant's arguments filed 22 January 2010 have been fully considered but they are not persuasive. Applicant argues that Hei in view of Brown, in view of Kobashi and in view of DeVries as applied to claims 37-41, 44-48, 51-54, and 56-63 above, and further in view of Hudak does not show does not show a controllable variable-volume with a moveable wall. The argument is not persuasive because Brown shows a controllable variable-volume processing chamber with a moveable wall.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

18 February 2010